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(54) Intravenous filter, and apparatus and method for pre-operative preparation thereof

(57) An intravenous filter comprises a cylindrical holder (1) and a thromboembolus-trapping device in the form of a set of resilient pins (4) secured in the holder. Each pin has an L-shaped grip (5) on its free end. An apparatus for preoperative preparation of the filter comprises an applicator capsule (9) attached to a catheter (11), a guide element (8) comprising conical (20) and a cylindrical (19) portions, a threaded stylet (21) and a collet clamp (17, 18). Preoperative preparation of the filter comprises matching the cylindrical portion of the guide element with the capsule bringing the stylet up through the guide element capsule, catheter and collet, screwing the filter on to the thread, retracting the filter through the guide element into the capsule and removing the guide element. The tightened collet prevents unwanted rotation/unscrewing of the filter.

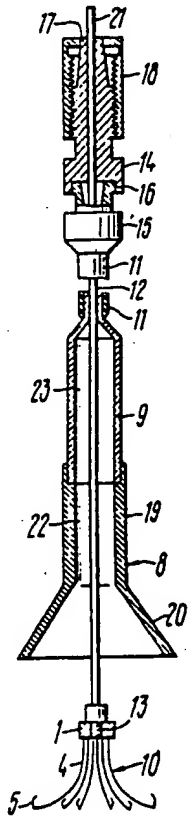

FIG. 6

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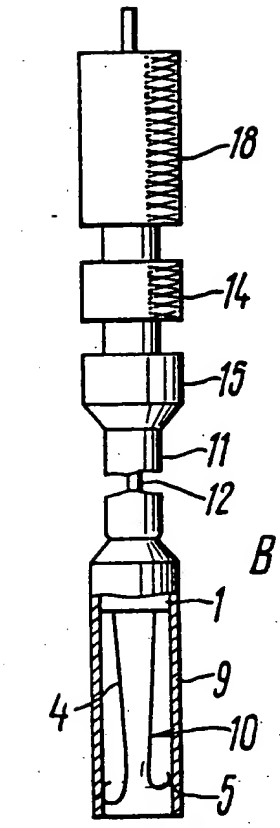

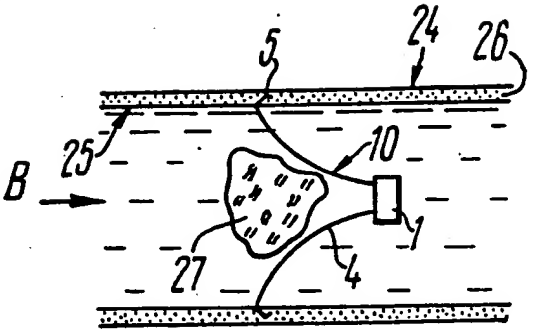

FIG. 8

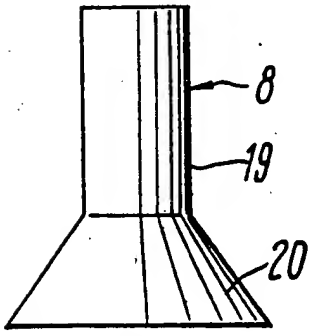

FIG. 7

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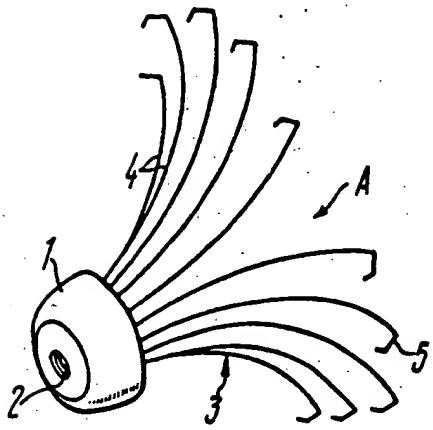

FIG. 1

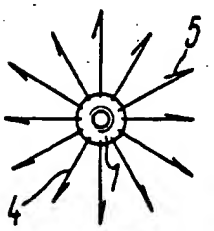

FIG. 2

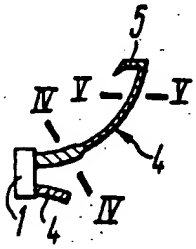

FIG. 3

FIG. 4

FIG. 5

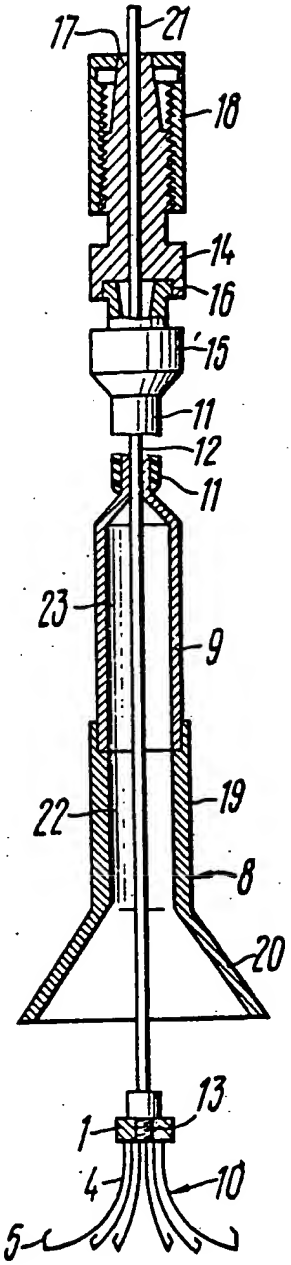

FIG. 6

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INTRAVENOUS FILTER, AND APPARATUS AND METHOD FOR PREOPERATIVE PREPARATION THEREOF

This invention relates to medical apparatus and, more particularly, to an intravenous filter, and an apparatus and method for the pre-operative preparation thereof.

The invention will prove useful for prevention of thromboembolism of the pulmonary artery by transdermic implantation of the intravenous filter through the subclavian or femoral artery.

Known in the prior art is an intravenous filter for therapy and prevention of thromboembolism of the pulmonary artery, comprising six wire elements, each curved into a complex configuration. The elements are secured in a holder. The filter is assembled manually in a cylindrical capsule. Each element is about 5 cm long and the entire filter is rather heavy.

The prior-art filter is complicated in design, and very heavy and cumbersome so that its implantation calls for surgical extraction of the jugular or femoral vein.

Besides, the construction and size of the filter deny its application for prevention of thromboembolism of the pulmonary artery by implanting it into the inferior vena cava, particularly when the upper part of the flotating thrombosis is localized under the renal veins while insufficient fixing and considerable weight of the filter often cause its dislocation, mostly in the distal direction of the inferior vena cava.

Also known in the prior art is an intravenous filter comprising an internally threaded cylindrical holder and a thromboembolus-trapping device secured on holder. The device is, essentially, a perforated silicone film reinforced by radially-arranged metal springs.

The springs are fastened at one end in the holder while their free ends protrude beyond the film, the free ends being pointed for fastening the filter in the walls of the inferior vena cava.

The filter is implanted into the inferior vena cava by means of an apparatus for the preoperative preparation of the filter. The apparatus is comprised of a guide element consisting of a cylindrical portion and a conical portion, and an applicator consisting of a filter-accommodating capsule, a catheter attached to the capsule, a stylet and a collet clamp. The stylet is located inside the catheter and capsule and is provided with a helical thread for holding the filter.

To assemble the filter, the stylet is passed through the capsule and the catheter, unthreaded end first. Then the filter is screwed onto the stylet thread, inserted into the cylindrical portion of the guide element through its conical portion, whereupon the filter is collapsed. Then the hole in the capsule is aligned with the hole in the cylindrical portion, the filter is moved into the capsule by the reverse traction of the stylet, whereupon the capsule is withdrawn from the guide element complete with the filter. Assembly

is completed by fixing the stylet with a collet clamp.

The basic drawbacks of this known filter include the blockage of the blood flow in the inferior vena cava due to its occlusion caused by clogging of the filter due to its geometrical shape and the "dead space" on its proximal surface, poor reliability of fixing in the vena cava and the need for surgery for its implantation resulting from the peculiar features of its construction.

By resorting to the known apparatus and method for preoperative assembly of the filter, the latter is placed into the applicator capsule so that its implantation becomes possible only through the right internal jugular vein (i.e., by the retrograde method). Besides, considerable forces have to be applied for collapsing the filter, and its insertion into the capsule may rupture the silicone film, thus involving a danger of a repeated thromboembolism of the pulmonary artery.

Another prior-art filter comprises a holder with resilient wire pins which are fastened inside to form a net. The pins are fastened together at a certain distance from the holder, then they diverge again. The end of each free pin has a supporting element. The holder is provided with a hook serving to assemble the filter before implantation and another hook located in the pin diverging zone. Between the two fastening points the resilient pins have a preset curvature which is ensured

by angular turning of the pins.

The filter is fixed in the inferior vena cava by means of supporting elements located on the free ends of the pins. The netting constituted by the pins overlaps the lumen of the inferior vena cava. Thus, preventing the thromboemboli from moving through.

This filter reaches 7 to 12 cm in length, is cumbersome and has two "dead zones" at the resilient pin attachment points, these zones being contributory to thrombogenesis; also fixing of the filter in the inferior vena cava by the supporting elements is unreliable and may lead to perforation of the venous wall and surrounding caval organs.

The preoperative assembly of the filter is carried out by the apparatus comprising a catheter, a system for inserting said catheter, a fixing hook and a holding hook.

The holding hook is passed through the catheter, fastened to the hook on the filter holder and the filter is pulled into the catheter, whereupon the filter is ready for use.

An object of the invention lies in providing an intravenous filter which would rule out perforation of the venous wall and surrounding caval organs.

Another object of the invention resides in providing an apparatus and method for preoperative preparation of the filter which would allow collapsing of the filter without disturbing its construction, which might

constitute a cause of repeated thromboembolism of the pulmonary artery.

This object is attained by providing an intravenous filter for the therapy and/or prevention of thromboembolism of the pulmonary artery which, according to the invention, comprises a cylindrical holder carrying a thromboembolus-trapping device made with a provision for fastening it in the walls of the inferior vena cava and having a set of resilient pins fastened at one end in the cylindrical holder so that these resilient pins form a cylindrical surface gradually transforming towards the free ends of the resilient pins into a conical surface and the free end of each resilient pin is provided with an L-shaped grip facing the cylindrical holder, outwardly with relation to the conical surface.

Each L-shaped grip can be turned relative to the axis of the intravenous filter and the resilient pins may vary in length.

It is practicable that each resilient pin has a variable cross section over its length, this cross section being circular at the point where the pin is fastened in the cylindrical holder, and flat at the point adjoining the L-shaped grip, the cross section of the intermediate portion being of the shape joining the circular and flat cross sections.

The resilient pins and the cylindrical holder may be made from the same biologically inert material.

It has been proved most suitable to select the

number of resilient pins on the basis of the inside diameter of the inferior vena cava and the possibility of trapping by the filter the smallest permissible size of the thromboembolus dangerous to the patient's life, said number ranging from 10 to 16.

This is also attained by providing an apparatus for preoperative preparation of the intravenous filter which, according to the invention, has a capsule accommodating the intravenous filter, a catheter attached to the capsule, a stylet located inside the catheter and capsule and provided with a thread for holding the intravenous filter, and a collet clamp interacting with the stylet, a guide element interacting with said applicator and forming a separable joint with the applicator capsule, and having a conical portion and a cylindrical portion, the latter having the same inside diameter as the applicator capsule and aligned with the capsule for making an integral inside space.

This is furthermore attained by providing a method for preoperative preparation of the intravenous filter which, according to the invention comprises the passing of the stylet through the catheter and capsule, aligning the cylindrical portion of the guide element with the applicator capsule, bringing the stylet threads outward through the guide element, screwing the intravenous filter on the thread, inserting the intravenous filter through the conical and cylindrical portions of the guide element into the applicator capsule

and taking the guide element off the capsule.

The herein-proposed technical solution permits reducing the traumatism of surgical intervention, curtailing the postoperative and renabilitation periods of the patients since the rilter is contributory to an early and effective recanalization of the thrombus-clogged venous bed.

Now the invention will be described by way of examples with reference to the accompanying drawings in which:

Fig. 1 illustrates an intravenous filter, according to the invention;

Fig. 2 - is a view along an arrow A in Fig. 1;

Fig. 3 shows one resilient pin in an enlarged view;

Fig. 4 is a section along a line IV - IV in Fig.3;

Fig. 5 is a section along a line V-V in Fig. 3;

Fig. 6 is an apparatus for preoperational preparation of the intravenous rilter according to the invention, in longitudinal section;

Fig. 7 is the same apparatus with the intravenous filter inserted into the capsule; and

Fig. 8 shows the intravenous rilter inserted into the inferior vena cava.

The intravenous rilter ror the therapy and/or prevention of thromboembolism of the pulmonary artery comprises a cylindrical holder 1 (Fig. 1) provided with a thread 2 and a thromboembolus-trapping device 3. The device 3 consists of a set of resilient pins 4

each fastened by one end in the holder 1. The number of resilient pins 4 is selected so as to suit the inside diameter of the inferior vena cava and to enable the filter to trap the smallest permissible thromboembolus dangerous to the life of the patient, said number ranging from 10 to 16. A number of pins less than ten fails to ensure reliable trapping of the thromboemboli while their number exceeding 16 is a physical impossibility in view of the technological peculiarities of fixing the pins in the holder of which the diameter is not over 3.2 mm.

Fig. 2 shows an embodiment of the filter with twelve resilient pins which is the optimum number.

The pins 4 are arranged near the holder 1 so that they form a portion of the cylindrical surface (Fig.1) which is transformed by the diverging pins 4 into a conical surface. The free ends of all the pins 4 have an L-shaped grip 5 intended for holding the filter in the vein.

The grip 5 faces the holder 1, outwardly in relation to the conical surface. Each grip 5 is turned relative to the filter axis through a certain angle as shown in Fig. 2 where the pins are shown to be of different lengths, e.g., alternating lengths, and form two rows. Each pin 4 has a variable cross section (Fig. 3). At the point where it is secured in the holder 1, it has a circular cross section 6 (Fig. 4). The portion adjoining the grip 5 has a flat cross section 7 (Fig. 5), the transition from the circular 6 to the

flat 7 cross-section being smoothly gradual.

The holder 1 and pins 4 are made of the same biologically inert material, for example widely used stainless steels of various grades having a modulus of elasticity of about 20500 kg/mm^2. The use of the same material for the holder 1 and pins 4 rules out probable electrochemical processes in the patient's organism which are apt to destroy the inserted intravenous filter.

The intravenous filter is prepared for operation by means of a special apparatus which is comprised of a guide element 8 (Fig. 6) and an applicator. The applicator incorporates a capsule 9 for accommodating the intravenous filter 10, a catheter 11 secured rigidly to a capsule 9, a stylet 12 located inside the catheter 11 and the capsule 9 and having a thread 13 for holding the filter 10, and a collet clamp 14 interacting with a pipe union 15 of the catheter 11.

The guide element 8 forms, jointly with the capsule 9, a detachable joint so that the element 8 can easily be removed from the capsule 9.

The collet clamp 14 has a cutout 16 which prevents angular motions of the stylet 12 in the course of the operation, a collet 17 and a nut 18.

The guide element 8 comprises a cylindrical portion 19 and a conical portion 20; the capsule 9 is matched with the cylindrical portion 19 and is of the same inside diameter as this portion.

Shown in Fig. 7 is the apparatus with the intravenous filter 10 inserted into the capsule 9. This is done as follows. The stylet 12 (Fig. 6, 7) is passed through the capsule and catheter 11, free end 21 first, the cylindrical portion 19 of the guide element 8 is aligned with the open end of the capsule 9 so that an internal space 22 of the element 8 constitutes a continuation of an internal space 23 of the capsule 9. At the same time the helical thread 13 of the stylet 12 is withdrawn beyond the limits of the element 8 and the holder 1 of the filter 10 is screwed on the thread. The grips 5 of the resilient pins 4 should face the conical portion 20 of the guide element 8 if the filter 10 is implanted through the R.H. interior jugular or subclavian veins (not shown in the drawing) and it should be directed away from the conical portion 20 of the guide element 8 if the filter is to be implanted through the femoral veins as shown in Fig. 6.

By an inverted traction of the stylet 12 the filter 10 is inserted through the conical 20 and cylindrical 19 portions of the guide element 8 into the capsule 9 (Fig. 7), the guide element 8 is removed from the capsule 9; then the stylet 12 is fixed against turning by the collet clamp 14 order to prevent accidental unscrewing of the filter in the course of the operation.

After a transdermic paracentesis a cannula (not shown in the drawing) is inserted under local anesthesia into the subclavian or femoral vein; then, under

the X-ray-cum-TV control the applicator capsule 9 is inserted through said cannula to the level of the lower edge of the body of the 2nd lumbar vertebra. Then the filter 10 is withdrawn by the stylet 12 from the capsule 9 and, pulling the entire applicator upward, the filter is fixed in the inferior vena cava. Now, by turning the collet clamp 14 a few times counterclockwise the applicator is dissociated from the implanted filter 10 and taken out of the vein complete with the cannula. The holder 1 of the filter 10 becomes installed proximally in relation to the grips 5 and the curved pins 4 secured in the holder 1 and symmetrically converging to the centre form an embolus localization zone. The puncture wound is protected by an aseptic sticker.

Shown in Fig. 8 is the filter 10 located inside an inferior vena cava, the apex of the conical surface of the pins 4 and the holder 1 of the filter 10 being arranged along the blood flow indicated by arrow B. Owing to their shape, the L-shaped grips 5 penetrate only through the internal surface of the wall 26 of the vena cava 24 and do not pierce it not only during the operation but also in the remote postoperative period.

When a thromboembolus 27 is localized by the filter 10 at the moment of embolism, the grips 5 do not move relative to a wall 26 of the vena cava 24 as they do in the prior-art intravenous filter.

The practical application of the invention per-

mits the employment of the X-ray endovascular prevention of thromboembolism of the pulmonary artery by the low-traumatic paracentesis method in extremely seriously ill patients suffering from floating thrombosis of main veins. The use of the herein-proposed intravenous filter, method and apparatus for its implantation reduces the time of surgical procedure 5 - 6 times which favours the outcome of the disease, cuts the time of treatment 4-5 times and retains the working fitness of the patients because of the absence of occlusion of the inferior vena cava after implantation of the proposed intravenous filter.

Presented below are the results of clinical tests of the hereinproposed intravenous filter.

Following the diagnostic angiographic examinations - cardiac catheterization, pulmoangiography, retrograde iliocavography the intravenous filters were transdermically implanted under local anesthesia for the purpose of prevention and treatment of the massive thromboembolism of the pulmonary artery in 39 patients surfering from embologenic thrombosis of the iliofemoral and iliocaval segments, including 27 retrograde implantations(21 through the left subclavian vein and 6 through the right internal jugular vein) and 12 antegrade implantations (9 through the right femoral vein and 3 through the left femoral vein). The patients operated up on included 17 (43.6%) females and 22 (56.4%) males aged 19 to 82.

Depending on the diameter of the infrarenal section of the inferior vena cava, determined by preoperative retrograde iliocavography, the intravenous filters of the following diameters were implanted:

23 mm diameter in 2 cases;

28 mm diameter in 23 cases;

32 mm diameter in 14 cases.

The angiographic intervention, i.e. transdermic implantation of the intravenous filter in the operated up on patients took 8 to 10 minutes and was undertaken at the closing stage of the diagnostic X-ray-contrast examinations, i.e., catheterization of the right cardiac cavities, pulmoangiography and retrograde iliocavography.

Before implantation, the intravenous filter was sterilized by autoclaving. The implanting apparatus was sterilized in a 6% solution of hydrogen peroxide.

In order to study the condition of the iliocaval segment, all operated-up on patients were subjected to control iliocavography within a period from 1 to 6 months. The analysis of the immediate and remote effects of endovascular prevention and treatment of thromboembolism of the pulmonary artery proves a high reliability of the method of transdermic implantation of intravenous filters. In our investigations the repeated thromboembolism of the pulmonary artery has developed in 1 (2.5%) operated-up on patient, the ba-

sic cause being an intraoperative error, i.e., wrong fixing of the filter which necessitated its repeated implantation. The postoperative mortality rate among the observed cases has constituted 7.4% and has been caused by the accompanying illnesses or the after-effects of the earlier developed massive thromboembolism of the pulmonary artery.

By the analysis of the clinicoangiographic and autopsy finding on 39 operated upon patients we have established that the intravenous filter does not get clogged, does not build up a pressure gradient in the vena cava and in 94.5% cases does not interfere with the main flow of blood through that vein.

CLAIMS

1. An intravenous filter for the therapy and/or prevention of thromboembolism of the pulmonary artery, comprising a cylindrical holder which carries a thromboembolus-trapping device made with a provision for being fastened in the walls of the inferior vena cava and comprising a set of resilient pins, one end of each pin being secured in the cylindrical holder so that the resilient pins form a cylindrical surface gradually transforming towards the free ends of the resilient pins into a conical surface, and the free end of each resilient pin having an L-shaped grip facing the cylindrical holder outwardly in relation to the conical surface.

2. An intravenous filter according to Claim 1, wherein each of the L-shaped grips is turned relative to the axis of the intravenous filter.

3. An intravenous filter according to Claim 1 or 2, wherein the resilient pins are of different length.

4. An intravenous filter according to any of Claims 1 to 3, wherein each of the resilient pins has a variable cross-section lengthwise, this cross-section being circular where the pin is secured in the cylindrical holder and flat at the portion adjoining the L-shaped grip, the cross-section of the intermediate portion being of the shape which joins toge-

ther the circular and flat forms.

5. An intravenous filter according to any of Claims 1 to 4, wherein the resilient pins and the cylindrical holder are made of the same biologically inert material.

6. An intravenous filter according to any of Claims 1 to 5, wherein the number of resilient pins is selected so as to suit the inside diameter of the inferior vena cava and to enable the intravenous filter to trap the smallest permissible thromboembolus dangerous to the life of the patient, said number ranging from 10 to 16.

7. An apparatus for preoperative preparation of the intravenous filter, comprising a guide element having a cyldrical portion and a conical portion and an applicator having a capsule to accommodate the intravenous filter, a catheter connected to the capsule and a stylet accommodated inside the catheter and capsule and having a thread for holding the intravenous filter, a collet clamp interacting with the stylet, and a guide element interacting with said applicator, said guide element forming a detachable joint with the applicator capsule and having a conical portion and a cylindrical portion which has the same inside diameter and matches with the applicator capsule.

8. A method for preoperative preparation of the intravenous filter comprising the insertion of the stylet through the catheter and capsule, aligning the

cylindrical portion of the guide element with the applicator capsule, bringing out the stylet thread through the guide element and screwing the intravenous filter on said thread, inserting the intravenous filter through the conical and cylindrical portions of the guide element into the applicator capsule, and taking the guide element off the capsule.

9. An intravenous filter for the therapy and/or prevention of thromboembolism of the pulmonary artery constructed as described above with reference to, and as shown in, Figs. 1 to 5 of the accompanying drawings.

10. An apparatus for preoperative preparation of the intravenous filter constructed substantially as above described with reference to, and as shown in, Figs. 6 and 7 of the accompanying drawings.

11. A method for preoperative preparation of the intravenous filter substantially as hereinbefore described.

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